

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-47 are pending in the subject application.

Claims 1-15, 18-25, 29-36, 39, 42, 43, 46 and 47 stand rejected under 35 U.S.C. §102 and/ or 35 U.S.C. §103. Claims 16, 17, 26-28, 37, 38, 40, 41, 44 and 45 were objected to as depending from a rejected base claim, however, the Examiner indicated that these claims would be allowable if appropriately re-written in independent form.

Claims 1, 29 and 42 were amended for clarity to reflect the usage of the claimed apparatus as not being an apparatus that is provided to localize a needle driver to a given location but rather the apparatus that drives the penetrating member or needle so that it resides within the target area. These claims also were amended so as to state that the penetrating members proximal portion also is translated in a direction towards the target area by the translation of the first arm. The method of claim 46 was amended so as to make clear that the method is for locating a penetrating member within the target area in a body and not a method embodied in the disclosed target systems disclosed in the cited patents.

Claims 2, 29 and 42 were amended for clarity so as to make clear that the long axis about which the penetrating member/ needle rotates is the long axis of the penetrating member/ needle.

Claims 3-5, 20, 21, and 30-33 were amended for consistency of language with the associated base claim and amongst the claims.

Claim 16 was re-written in independent form as suggested by the Examiner.

Claim 47 was amended to reflect changes in the base claim.

Claims 48-55 were added to claim embodiments/ aspects of the present invention.

The amendments to the claims are supported by the originally filed disclosure.

The drawing figures were objected to and correction required. Amended drawing figures are being submitted herewith that address certain of the drawing objections. The specification was amended so as to address other of the drawing objections and comments are provided below to address the objections without amendment. The amendments to the specification and/ or drawing figures do not introduce new matter because they either are editorial in nature or are supported by the originally filed disclosure.

35 U.S.C. §102 REJECTIONS

Claims 1-9, 13-15, 18-25, 29-34, 36, 39, 42 and 46-47 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated for the reasons provided on pages 2-5 of the above-referenced Office Action. Because claims were amended in the foregoing amendment, the following discussion refers to the language of the amended claim(s). However, only those amended features specifically relied on in the following discussion shall be considered as being made to overcome the prior art reference. The following addresses the specific rejections provided in the above-referenced Office Action.

CLAIMS 1-9, 13-15, 18-25, 29-34, 36, 39, 42 & 46-47

Claims 1-9, 13-15, 18-25, 29-34, 36, 39, 42 and 46-47 stand rejected as being anticipated by Paltieli [USP 5,647,373] for the reasons provided on pages 2-4 of the above referenced Office Action. Applicants respectfully traverse.

As indicated in the subject application (e.g., see pages 9-10 thereof), the penetrating member driver 100 can be used in connection with any of a number of manual, motorized, or robotic targeting apparatuses or systems as is known to those skilled in the art. It is further indicated therein that in use these manual, motorized or robotic targeting apparatuses or systems are operated so the needle 50 axis being held in the penetrating member driver 100 is positioned and oriented so that it points at the entry point of the body and also so that the needle is oriented such that it translates along the translational axis to the target area.

In contrast to the present invention, the elements of the cited reference, Paltieli, referred to in the grounds for rejection (e.g., elements identified by reference numerals 42, 43 as first and second arms) are not elements of an apparatus as is claimed by Applicants. Rather the structural elements being identified are those of a motorized, or robotic targeting apparatus or system that is used by the physician to the manipulate the needle guide 5 so as to place the needle 6 on the skin close to the target in the desired direction (e.g., see Abstract and Figure 1 thereof). Paltieli further states that as soon as the physician is aware of the correct aiming position of the needle, he inserts the needle into the body until the needle point is on the target as viewed on the ultrasound imaging device.

Thus, it can be seen that the element that most closely corresponds to the apparatus of the present invention in Paltieli is the needle guide 5 and that the other identified elements in support of the rejection do not correspond to or equate to elements or features of the present invention. It also is clear that Paltieli discloses an entirely different device, composed of parts distinct from those of the claimed invention, and operates in a different way than the claimed invention. Thus, it can hardly be said that the cited reference anticipates any of the claims of the present invention.

While Applicants believe that language of pending claim 1 is distinct from the cited reference as indicated above, in the interests of advancing prosecution claim 1 was amended for clarity so as to clearly indicate that the apparatus of the present invention is not a manual or motorized targeting system such as that disclosed in Paltieli and that the translation of the first arm thereby causes the penetrating members proximal portion to be translated in a direction towards the target area.

As to claims 29 and 42 these claims further provide that an apparatus of the present invention includes a second arm coupled to the first drive mechanism so as to cause the first arm to translate towards the second arm. It is clear from figure 2 in Paltieli that one link 41 forming the so-called first arm is rigidly attached at one end and the other link 42 making up the so-called first arm is arranged so it is extendable lengthwise from within the first link. Given such an arrangement it can hardly be said that the so-called first arm disclosed in Paltieli is physically capable of being translated towards the second arm. The discussion in Paltieli merely describes how the moving links and pivotable mounts (e.g., 8, 44) can be used to change the angle of the

needle axis (see col. 4, lines 43-61) by changing the respective lengths of the so-called first and second arms.

Claims 29 and 42 also further include a second drive mechanism for rotating the penetrating member or needle about a long axis of the penetrating member/ needle. As indicated above, Paltieli indicates that after the needle is positioned with respect to the skin, the needle is inserted manually by the physician or by a third servo motor (it should be noted that the third servo motor is not shown in any of the drawing figures of Paltieli). It also is clear from the discussion in Paltieli that the alleged second drive mechanism (servo-motor 45) is used to move the bar or link 42 of the so-called first arm. Paltieli nowhere shows or describes that this servo motor 45 is coupled to the needle 6 within the needle guide 5 nor describes anywhere that the needle is rotated about its long or longitudinal axis by this servo motor.

Thus, Applicants believe that claims 29 and 42 are distinguishable from the cited reference for the reasons provided above regarding claim 1 as well as the foregoing reasons provided above for claims 29 and 42. While Applicants believe that language of pending claims 29 and 42 is distinct from the cited reference as indicated above, in the interests of advancing prosecution claims 29 and 42 were amended for clarity so as to clearly indicate that the apparatus of the present invention is not a manual or motorized targeting system such as that disclosed in Paltieli and that the translation of the first arm thereby causes the penetrating members proximal portion to be translated in a direction towards the target area.

Applicants also amended claim 46 in a similar fashion so as to more clearly indicate that the method of the present invention is not the same as the method embodied in a manual or motorized targeting system.

Applicants respectfully submit that at least for the foregoing reasons each of the other rejected claims, claims 2-9, 13-15, 18-25, 30-34, 36, 39, and 47 are distinguishable from the cited art at least because of their dependency from an independent claim that is considered allowable. Applicants also would note that some of the remarks provided above regarding claims 29 and 42 also apply to distinguish some of these claims (e.g., claim 2) from the cited art as well.

It is respectfully submitted that claims 1-9, 13-15, 18-25, 29-34, 36, 39, 42 and 46-47 are patentable over the cited reference for the foregoing reasons.

CLAIMS 1-6 & 46-47

Claims 1-6 and 46-47 stand rejected as being anticipated by Stoianovici (WO98/36688) for the reasons provided on page 4-5 of the above referenced Office Action. Applicants respectfully traverse.

In the foregoing discussion regarding Paltieli, Applicants indicated that the elements in that grounds of rejection are not elements of the apparatus being claimed by Applicants but rather the structural elements being identified were those of a motorized, or robotic targeting apparatus or system. Applicants would submit that the foregoing remarks regarding the Paltieli reference apply equally for the Stoianovici reference as the elements being cited to Stoianovici in support of the within grounds of rejection also are structural elements of a motorized, or robotic targeting

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apparatus or system. As such, Applicants submit that the motion transmission system disclosed in Stoianovici does not disclose the invention claimed by Applicants.

As also indicated above, notwithstanding that Applicants believe that language of the pending claims is distinct from the cited reference as indicated above, in the interests of advancing prosecution claim 1 was amended for clarity so as to clearly indicate that the apparatus of the present invention is not a manual or motorized targeting system such as that disclosed in Paltieli or Stoianovici and that the translation of the first arm thereby causes the penetrating members proximal portion to be translated in a direction towards the target area and that claim 46 was similarly amended as well.

As to the suggestion that Stoianovici discloses in fig 1 thereof a second drive mechanism Applicants would respectfully disagree as figures 6-7 thereof illustrate that rotational motion is used to cause the needle 7 to translate; not rotate.

It is respectfully submitted that claims 1-6 and 46-47 are patentable over the cited reference for the foregoing reasons.

The following additional remarks shall apply to each of the above.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as

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required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above identified claims are not anticipated by either of the two cited references.

In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). In concluding that the '770 Patent did not anticipate the claims, the Federal Circuit in *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, at 221 USPQ 485-486, further provides that:

The '770 patent discloses an entirely different device,
composed of parts distinct from those of the claimed invention, and
operating in a different way to process different materials differently.
Thus, there is no possible question of anticipation by equivalents.
Citations omitted.

It is clear from the foregoing remarks, that the allegedly corresponding elements disclosed in Paltieli or Stoianovici do not in fact correspond to the elements of the claimed invention. It also is clear that the apparatus described in either of these two references functions and operates in a different manner from that of the claimed invention. As also indicated above, the method disclosed and taught in either of these two references is completely different from that claimed and taught by

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Applicants. Thus, there can be no disclosure or teaching in either of the two references of Applicants' invention.

It is respectfully submitted that for the foregoing reasons, claims 1-9, 13-15, 18-25, 29-34, 36, 39, 42 and 46-47 are patentable over either of the two (2) cited reference(s) and thus satisfy the requirements of 35 U.S.C. §102. As such, these claims, including the claims dependent therefrom are allowable.

35 U.S.C. §103 REJECTIONS

Claims 10-12, 35 and 43 stand rejected under 35 U.S.C. §103 as being unpatentable over Paltieli for the reasons provided on page 5 of the above-referenced Office Action. Applicants respectfully traverse as discussed below. Because claims were amended in the instant amendment, the following discussion refers to the language of the amended claims. However, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference.

Each of claims 10-12, 35 and 43 depend respectively from one of independent claims 1, 29 or 42. As indicated above, Paltieli does not disclose the apparatus of any of claims 1, 29 and 42. It also is submitted that Paltieli does not teach or suggest the apparatus of any of claims 1, 29 and 42 nor does the reference offer any teaching, suggestion or motivation for modifying the apparatus disclosed in Paltieli so as to yield the apparatuses of claims 1, 29 or 42. As such, at least because of their dependency from an independent claim believed to be allowable, each of claims 10-12, 35 and 43 also are considered to patentable over the cited art.

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It is respectfully submitted that for the foregoing reasons, claim(s) 10--12, 35 and 43 are patentable over the cited reference(s) and satisfy the requirements of 35 U.S.C. §103. As such, these claims, including the claims dependent therefrom are allowable.

CLAIMS 16, 17, 26-28, 37, 38, 40, 41, 44 and 45

In the above-referenced Office Action, claims 16, 17, 26-28, 37, 38, 40, 41, 44 and 45 ere objected to as being dependent upon a rejected base claim. It also was provided in the above-referenced Office Action, however, that these claims would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claim(s).

Claim 16 was re-written in the foregoing amendment so as to be in independent form and to include all the limitations of the base claim there being no intervening claim(s). Claim 17 was not re-written in independent form as suggested by the Examiner as it depends from claim 16. Accordingly, claims 16-17 are considered to be in allowable form.

In as much as Applicants believe that the base claims, claims 1, 29, 42 and 46 are in allowable form, claims 26-28, 37, 38, 40, 41, 44 and 45 were not re-written in independent form as suggested by the Examiner. Applicants, however, reserve the right to later amend the subject application so as to present any one or more of these claims in independent form or to add one or more independent claims that contain the limitations of any one or more of claims 26-28, 37, 38, 40, 41, 44 and 45.

CLAIMS 48-55

As indicated above, claims 48-55 were added to more distinctly claim embodiments/aspects of the present invention. These claims are clearly supported by the originally filed disclosure, including the originally filed claims. It also is respectfully submitted that these added claims are patentable over the cited prior art on which the above-described rejection(s) are based.

DRAWING OBJECTIONS

The Examiner objected to drawing figures for the reasons provided on page 2 of the above-referenced Office Action. Specifically the drawing figures stand objected to because reference numerals 170, 175 and 188 are not shown in the drawing figures but are referred to the subject application.

As to the reference numeral 188, Applicants direct the Examiner's attention to Fig. 5.

As to reference numeral 175, Fig 5 is being amended herewith so as to address the Examiner's objection.

As to reference numeral 170, Applicants amended the specification in the foregoing amendment to replace those occurrences of numeral 170 with numeral 180 so as to be consistent with the drawing figures and consistent with other discussion of the subject application. Thus, further amendment of the identified drawing figures is not believed to be necessary to address this particular concern.

During preparation of the within Response, Applicants also identified some other areas where the drawing figures and/ or specification should be revised to resolve other possible objections to the drawing figures and/ or inconsistencies with the drawing figures and

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specification. As to the drawing figures, the second occurrence of reference numeral 190 on Figs. 2 and 3 is being changed to read as reference numeral 189 and the specification is being amended to indicate that this reference numeral corresponds to the drive belt.

Attached herewith are replacement sheets including Figs. 2, 3 and 5 in which the drawing figures were amended as indicated above to address the Examiner's objections and to resolve other possible objections and/ or inconsistencies. As such the as-amended drawing figures are considered acceptable.

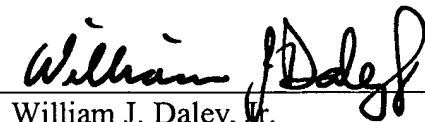
It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Because the total number of claims and/or the total number of independent claims post amendment now exceed the highest number previously paid for, a check is enclosed herewith for the required additional fees. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
Edwards & Angell, LLP

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